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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,872	10/12/2001	Anthony Toranto	ANGL-06602	2860

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EXAMINER	
COOK, LISA V	
ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/976,872	TORANTO ET AL.	
	Examiner	Art Unit	
	LISA V. COOK	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,20-24 and 74* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,20-24 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114 was filed in this application after a decision by the Board of Patent Appeals and Interferences, but before the filing of a Notice of Appeal to the Court of Appeals for the Federal Circuit or the commencement of a civil action. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 2/19/08 has been entered.

Amendment Entry

2. Applicant's amendment to the claims filed 2/19/08 is acknowledged. Claim 1 was modified. Claims 16-19 and 25-73 have been canceled. New claim 74 was added. Accordingly, claims 1-15, 20-24, and 74 are pending and under consideration.

Priority

3. If applicant desires priority under 35 U.S.C. 120 to application number **09/398,552 filed 09/17/1999, now abandoned**, and application number **09/698,306 filed 10/27/2000, now US Patent Number 6,730,494**; a specific reference to the earlier filed application must be made in the instant application.

For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression *"now Patent No. _____" should follow the filing date of the parent application*. If a parent application has become abandoned, the expression *"now abandoned"* should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii).

This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c).

A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c).

The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

4. Although the instant specification contains a specific reference to application numbers **,** it does not include the status. The instant application should be updated to recite application number application number **09/398,552 filed 09/17/1999, now abandoned**, and application number **09/698,306 filed 10/27/2000, now US Patent Number 6,730,494**. Please add the status to the disclosure.

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Oath/Declaration

6. A new oath or declaration is required because application number 09/393,552 is listed on the Declaration (see paper filed 2/15/02). The correct application number is **09/398,552**. Appropriate correction is required.

The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Specification

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

8. The use of the trademarks has been noted in this application. (.i.e. COCAINE -page 4, line 10 and POLYURETHANE-page 31, line 23). All trademarks in the disclosure should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-15, 20-24 and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-8, 10-15, 20-24, and 74 are rejected as being dependent on claim 1.

A. Claim 1 is vague and indefinite because it is not clear what the term "potassium iodide chromagen" will encompass. In particular, it is not clear if Applicant intends to claim potassium iodide as the chromagen or does "potassium iodide chromagen" read on a composition requiring potassium iodide and an additional chromagen? As recited the metes and bound of the claim can not be determined. The term "potassium iodide chromagen" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is suggested that the claim merely recite "potassium iodide" in order to obviate this rejection.

B. Claim 9 is vague and indefinite because it is not clear as to how many chromagens will be found on the reaction site. Claim 1 appears to comprise a potassium iodide chromagen. Thus the recitation of the reaction site comprising a chromagen in claim 9 is ambiguous. If Applicant intends to mean that the reaction site comprises an *additional* chromagen, then that should be clearly set forth in the claims. Please clarify.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claim 1 and dependent claims 2-15, 20-24, and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "potassium iodide chromagen" however support for this has not been found in the instant specification. Although the specification teaches the use of potassium iodide as the chromagen, there is no support for "potassium iodide chromagen". Therefore this appears to be new matter. Applicant is invited to show support for the newly added claim limitation.

11. Claim 74 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 74 recites " a color change occurs when said **ethanol concentration corresponds** to blood alcohol concentrations of 0.4%". Applicant has directed examiner to page 45 lines 5-27 for support for the new claim. However, support is not found.

Specifically, the cited section of the disclosure does not recite ethanol or it's corresponding to blood alcohol concentrations. The disclosure teaches that *an alcohol* (not ethanol) sample concentration *equivalent* (not corresponding) to a blood alcohol concentrations of 0.04% would not change color at concentration *significantly under* (not below) 0.04% but would change color at concentrations at or above 0.04%. See page 45 lines 7-10. It is suggested that the same language recited in the specification be included in the claim, in order to obviate the rejection. This will eliminate ambiguity. Appropriate correction is required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 1-4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only).

Sangha discloses a method of collecting, identifying, and quantifying saliva. The presence of the peroxidase enzyme (an analyte) in saliva is reacted with a peroxide to oxidize the "leuco" or colorless form of a dye or other indicator and produce a colored reaction for measurement (claims 1 and 2). See column 4 lines 22. In a second enzymatic method for verifying the presence of saliva a free colored chromagen that is visible to an observer is produced (claim 11). See column 4 lines 23-34.

Various colored chromagens may be utilized in the invention. See column 6 lines 1-25. The use of the color indicators in the collection probe of this patent allows for confirmation of saliva collection as well as sample collection amounts. See abstract and column 4 lines 19-22.

A swab is placed in the mouth of a subject and collected. The swab is then transferred to application zones onto an absorbent layer. See column 5 lines 44-54. The saliva sample is collected on a sample probe comprising a support stick with an absorbent attached to one end of the support (claims 3 and 4). This has been interpreted to read on Applicant's test strip as defined by the specification on page 16 line 26 through page 17 line 2 wherein "the test assay" comprises a simple test strip containing a reactive site at one end," and exemplified in figure 18.

Although Sangha disclose the measurement of the peroxidase enzyme found in saliva they are silent with respect to the use of potassium iodide. However, this is deemed inherent to the teachings of Sangha because potassium iodide is a known substrate for peroxidase activity in saliva. This is evidenced by the English abstract to Levitskii et al. In addition, Sangha discloses the utility of iodide ions in column 12 line 50, which encompasses the potassium iodide of the instant claims.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Spring et al. (US Patent #5,643,721).

Please see over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only)as set forth above.

Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) differ from the instant invention in failing to particularly teach the reaction site comprising a biosensor.

However, Spring et al. teach biosensors comprising immobilizing mediums (test strips). See abstract and column 8 through column 11. The immobilizing mediums comprise the appropriate bioreagents and is useful in any assay format. See column 2 lines 51-67 for example. The biosensors can be employed with various “test samples”, including saliva. See column 4 lines 61-67.

The immobilization medium taught by Spring et al. can be employed for the preparation of biosensor devices, in which the reaction of the enzyme substrate is monitored directly by an electrochemical or optical sensor. See column 11 section V.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the reaction site (immobilizing medium) of Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) into the biosensor of Spring et al. because Spring et al. taught that his sensor allowed for direct assay measurement with an electrochemical or optical sensor. See Spring et al. column 11 section V.

One of ordinary skill in the art would have been motivated to employ biosensors in order to generate precise and accurate data for the analyte of interest.

III. Claims 6 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Bogema (US Patent #6,248,598).

Please see over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only)as set forth above.

Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) differ from the instant invention in failing to particularly teach an antibody in the reaction site and the amount of time the reaction site should be held in a patient's mouth in order to generate a detectable signal.

However, Bogema teaches a test strip device that can be utilized to measure at least one analyte in saliva samples. The device allows for the simple collection and simultaneous analysis of saliva without the need for saliva manipulation or the use of instrumentation outside of the device. See column 3 lines 30-39, for example.

Bogema teaches that combining the collection of specimen and the analysis into a single device with no operations or reagents will greatly simplify the test and allow untrained users to perform the collection and analysis. See column 3 lines 51-54. The device can be composed of various binding partners including antibodies (claim 6). See column 9 lines 34-38. A portion of the solid support (strip) includes a visual reading area on which is directly bound a binding partner, a protein such as an antibody that specifically binds an analyte-that comprise of a colored label (col. 8, lines 12-23). The results can be seen with the naked eye (col. 8, lines 52-54).

The device comprises a solid support (strip) with suitable absorbent material which is inserted into a patient's mouth for about 10-120 seconds to absorb saliva (claims 12 and 14-15). See column 7 lines 15-65.

It would have been obvious to one of ordinary skill in the art at the time of the invention to place the reaction site in a subject's mouth from about 10 to 120 seconds as taught by Bogema into the saliva anaysis method of Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) because Bogema taught that his device allows for the simple collection and simultaneous analysis of saliva without the need for saliva manipulation or the use of instrumentation outside of the device. See column 3 lines 30-39, for example.

Bogema teaches that combining the collection of specimen and the analysis into a single device with no operations or reagents will greatly simplify the test and allow untrained users to perform the collection and analysis. See column 3 lines 51-54.

With respect to the detectable signal being generated faster than 5 seconds in the subjects mouth (claim 13), it is noted that Bogema discloses a time frame from *about* 10 seconds (reading on less than 5 seconds). See column 7 lines 15-65. Absent evidence to the contrary it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to optimize the time of signal detection in order to generate rapid results.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

IV. Claims 5, 8-10, 20-22 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Titmas (US Patent #5,563,073).

Please see over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only)as set forth above.

Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) differ from the instant invention in failing to particularly teaching that the analyte comprises an alcohol moiety that is reactive with an enzyme, wherein the measured concentrations are indicated by a color change of 0.04% blood alcohol concentration.

Titmas teaches a personal blood alcohol level testing kit. The kit includes pads (strips) with at least one alcohol-sensitive enzyme (i.e. alcohol oxidase enzyme and alcohol peroxidase enzyme), at least one dye, and at least one buffer. For example, see column 6 line 10-11. The pad changes color when it is contacted with saliva containing alcohol. See column 2 lines 61-67. The measurement of alcohol level in saliva is taught to be approximately 98% accurate. See column 2 line 2. The pads can be placed into the mouth for saturation or dipped into a collection cup. see column 3 lines 36-45. Although Titmas is silent with respect to ethanol and glucose detection, the patent teaches alcohol measurements which encompass ethanol and glucose (or the sugar alcohols).

Titmas teaches that an alcohol sensitive pad that noticeably changes colors at blood alcohol levels of 0.04% and 0.08% by volume blood alcohol levels may be desirable because Federal law sets the limit for drunk driving at 0.04% by volume blood alcohol and most states set the limit for drunk driving at 0.08% by volume blood alcohol. Thus the color change at these alcohol levels will easily inform the user that they are considered by either Federal or state law to be a drunk driver (intoxicated). See column 6 lines 45-53.

It would have been obvious to one of ordinary skill in the art at the time of the invention to detect alcohol blood concentrations with an enzymatic testing pad with a color change at 0.04% blood alcohol levels as taught by Titmas in the saliva testing method of Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) because Titmas taught that the measurement of alcohol levels in saliva is approximately 98% accurate. See column 2 line 2. The enzymatic reaction pads in Titmas utilized alcohol sensitive pads that noticeably changes color at blood alcohol levels of 0.04% and 0.08% by volume blood alcohol levels. These levels are set by Federal law and state laws for drunk driving. Thus the color change at these alcohol levels would easily inform the user if they are considered by either Federal or state law to be a drunk driver (intoxicated). See column 6 lines 45-53.

One of ordinary skill in the art would have been motivated to measure their blood alcohol level in order to prevent injury from being intoxicated or arrests for driving under the influence of alcohol.

V. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) in view of Tabb et al. (US Patent #4,440,724).

Please see over Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) as set forth above.

Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) differ from the instant invention in failing to particularly teaching that the analyte comprises a Ketone body.

However, Tabb et al. teach methods utilizing test strips to detect ketone bodies in human fluids. Ketone body measurements are taught to be useful in the early diagnosis of diseases such as diabetes and renal insufficiency, and uremia. See column 1 lines 14-23.

The method and strips taught by Tabb et al. allow for the accurate measurement of ketone bodies over a wide range of acidity and alkalinity. See column 1 lines 6-12 and column 2 lines 64-67. Multiple reagents including a chromagen are impregnated onto a bibulous strip. See column 3, especially line 17. The tests results provided a system which is stable in response to temperature variations and humidity variations, and which maintained the ability to resolve or differentiate among various levels of ketones. See column 6 lines 30-35.

It would have been obvious to one of ordinary skill in the art at the time of the invention to measure ketone bodies as taught by Tabb et al. in the anaysis method of Sangha (US Patent #5,334,502) as evidenced by Levitskii et al. (Ukrainskii Biokimicheskii Zhurnal, 1979, Vol.51, No.3, pages 289-292, English Abstract Only) because Tabb et al. taught Ketone body measurements are useful in the early diagnosis of diseases such as diabetes and renal insufficiency, and uremia. See column 1 lines 14-23. Further, the tests results exemplified that ketones could be measurements were stable in response to temperature variations and humidity variations. While maintaining the ability to resolve or differentiate among various levels of ketones. See column 6 lines 30-35.

Response to Arguments

Applicant's arguments and amendments have been carefully considered and found persuasive. New rejections have been applied accordingly.

14. For reasons aforementioned, no claims are allowed.

15. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
Patent Examiner
Art Unit 1641
Remsen 3C-59
3/27/08

/Lisa V. Cook/

Primary Examiner, Art Unit 1641